

### REMARKS

In an Office Action dated April 6, 2004, the Examiner has rejected claims 25-40 in the pending application. Reconsideration of this application and allowance of the claims is respectfully requested in view of the following remarks.

Claims 25-27 were rejected under 35 U.S.C. §102(e), as being anticipated by On (US 6,319,514 B1). According to the Examiner the reference clearly shows a two component composition wherein the active ingredients would be ibuprofen and domperidone and are therefore rejected for the same reasons as set forth in the Office Action mailed July 14, 2003. Further, the Examiner asserts that applicant's amendment to claim 25 showing the amount of domperidone of 0.1 to 20% by weight does not constitute a patentable distinction. According to the Examiner the reference shows the particular combination of ibuprofen and domperidone, and one skilled in the art would envision effective amounts of domperidone to elicit the desired activity.

Applicants submit that the invention is different from the disclosure of On and is not inherently disclosed by the reference. As the Examiner acknowledged, the currently claimed invention requires that the composition comprises a mixture of an ibuprofen medicament, 0.1 to 20% by weight of a domperidone medicament based on the total weight of the composition, and a carrier material, as in amended claim 25. In particular, the amount of a domperidone medicament is included in the composition in an amount of 0.1 to 20% by weight based on the total weight of the composition. Applicants submit that the On reference however, does not teach or suggest anything about the weight percentages of the domperidone medicament in the

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composition. Further, contrary to the Examiner's assertion one skilled in the art could not readily ascertain the range at which domperidone is effective in alleviating the adverse gastrointestinal effects and at the same time increasing the absorption of ibuprofen when used together in a medicament. Therefore, applicants submit that On lacks a required element as claimed in the current application, which element is not inherent from the On reference. Thus, claims 25-27 are not anticipated by On either directly or inherently. Applicants therefore respectfully submit that the presently claimed invention of claims 25-27 is not anticipated under 35 U.S.C. §102(e) by On (US 6,319,514 B1). Withdrawal of the rejection is respectfully requested.

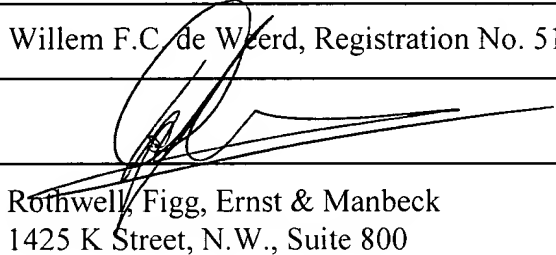
Claims 25-40 were rejected under 35 U.S.C. §103(a) as being unpatentable over On (US 6,319,514 B1). According to the Examiner the reference shows the particular composition comprised of ibuprofen and domperidone, but does not show the amount by weight of domperidone of 0.1 to 20%. The Examiner asserts that it would be reasonable for one skilled in the art with a knowledge of the effect domperidone has on gastric motility to determine adequate amounts of domperidone to use in conjunction with ibuprofen without undue experimentation. According to the Examiner one skilled in the art would arrive at the amounts of domperidone claimed to use with ibuprofen from the desire to provide optimum pain relief while minimizing the adverse gastrointestinal effects.

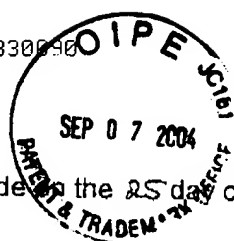
Applicants submit that The Boots Company Plc is the owner of a 100% interest in the current patent application as set forth in the assignment attached hereto in appendix A. Further, applicants submit that Dr. On entered into an assignment agreement with The Boots Company Plc regarding United States Patent application 08/859,185 of which United States Patent

application 09/492,164 is a continuation. The assignment agreement is attached hereto in appendix B for the Examiner's review. The US Patent No 6,319,514 B1, referenced by the Examiner as prior art under 35 U.S.C §102(e)/103(a) issued from this US patent application 09/492,164. Therefore, applicants seek to disqualify US Patent No 6,319,514 B1 as prior art for purposes of 35 USC §103. Accordingly, applicants respectfully request withdrawal of the rejection of claims 25-40.

Applicants submit that the present application is now in condition for allowance.

Reconsideration and favorable action are earnestly requested.

RESPECTFULLY SUBMITTED,					
NAME AND REG. NUMBER	Willem F.C. de Weerd, Registration No. 51,613				
SIGNATURE				DATE	9/7/04
Address	Rothwell, Figg, Ernst & Manbeck 1425 K Street, N.W., Suite 800				
City	Washington	State	D.C.	Zip Code	20005
Country	U.S.A.	Telephone	202-783-6040	Fax	202-783-6031



A. Executed

This Agreement is made on the 25 day of JULY 1998 between

- (1) THE BOOTS COMPANY PLC whose registered office is situate at Nottingham NG2 3AA ("Boots") and
- (2) DR NINH ON OF 36 Spray Street Woolwich London SE18 6AG ("Dr On").

#### WHEREAS

- (A) Dr On has carried out the Research into the anti-migraine effects of the Product the results of which are more particularly set out in the Patent Application.
- (B) Boots is willing to pay certain sums in consideration of Dr On assigning the benefit of the Research and the Patent Application to Boots and granting further rights to Boots all as more particularly set out in this agreement.

NOW IT IS HEREBY AGREED AS FOLLOWS:-

#### 1. DEFINITIONS

In this Agreement the following words shall have the following meanings:-

"Assignment" shall mean the Patent Application Assignment set out in the Schedule hereto;

"Confidential Information" shall mean all information:-

- (a) provided both directly or indirectly to Dr On by or on behalf of Boots and/or relating to Boots or any other company in the Group; or
- (b) relating in any way to the Product including but not limited to the formula

thereof) the Patent Application the  
Research and/or the Information;

"Group"

shall mean the group of companies comprised  
of The Boots Company PLC and all its  
subsidiaries (as defined in Section 736 of the  
Companies Act 1985);

"Information"

shall mean all material, reports, ideas and  
other information (in whatever media)  
generated by the Research and/or the Patent  
Application;

"Intellectual Property Rights"

shall mean copyright, patent, design right,  
moral right, registered design or similar rights;

"Net Sales"

shall mean the total figure calculated by  
multiplying:-

(a) the number of units of the Product sold  
by Boots in the relevant Quarter under  
the Patent Application and/or any  
Patent resulting therefrom to any third  
party which is not a member of the  
Group less the number of units of  
Product returned or destroyed in such  
Quarter by purchasers of such Product  
in circumstances where such  
purchasers receive a repayment credit  
or replacement in respect of such  
returned or destroyed Product; by

(b) the Net Selling Price;

**"Net Selling Price"**

shall mean the price charged by Boots on the sale of the Product under the Patent Application and/or any Patent resulting therefrom to any wholesalers or distributors which are not members of the Group net of sales tax value added tax or any similar tax and further net of any discounts granted;

**"Patent Application"**

shall mean the United Kingdom Patent Application Number 9613410.1 dated 23 June 1996 and relating to the Product;

**"Product"**

shall mean anti-migraine products containing ibuprofen PhEur and domperidone PhEur as more particularly described in the Patent Application;

**"Quarter"**

shall mean any period of three consecutive calendar months ending on 31 March 30 June 30 September or 31 December as the context so requires; "Quarterly" shall be construed accordingly

**"Research"**

shall mean the research which has been carried out by Dr On in connection with and resulting in the Patent Application;

**" United States Patent Application"** shall mean the United States Patent Application Number 08/859,185 dated 20th May 1997 and relating to the Product.

## 2. ASSIGNMENT

2.1 In consideration of the payment by Boots to Dr On of the sum of £10,000 (receipt of which is hereby acknowledged by Dr On) Dr On hereby assigns

- (a) to Boots the Patent Application by means of the Assignment; and
- (b) to Boots or such other person firm or company as Boots may nominate the Intellectual Property Rights and all other rights title and interest in and to the Information and shall do all such acts and things as Boots deems necessary or reasonably desirable to vest such rights in Boots including when and if necessary the filing or assistance with the filing of any further or other patent application or other procedure the purpose of which is the protection of such rights in the Information.

2.2 Dr On shall forthwith upon execution of this Agreement:-

- (a) execute and deliver to Boots the Patent Application;
- (b) deliver to Boots all Information which may be in her possession or control and no copies of any such things shall be retained by her.

2.3 Dr On shall promptly upon request from Boots sign confirm and/or authenticate all or any forms declarations and papers properly or reasonably required by any Patent Office in support of the Patent Application the United States Patent Application and/or any divisional or continuation or related applications in respect thereof and will promptly deliver the same to Boots or its nominee.

2.4 Dr On irrevocably appoints Boots to be her attorney or agent in her name and on her behalf to do all such other acts and things and to sign all such other deeds and documents as may be necessary in order to give Boots the full benefit of the provisions of this Agreement.

3. UNITED STATES PATENT APPLICATION

- 3.1 Dr On hereby expresses her willingness to assign the United States Patent Application to Boots or such other person firm or company as Boots may nominate such assignment to be upon fair and reasonable commercial terms.
- 3.2 In consideration of the mutual promises herein Dr On hereby undertakes not to:-
- (a) enter into any negotiations or discussions with any other person firm or company relating to an assignment transfer sale licence or other grant of rights in or to the United States Patent Application during the period of 12 months following the date hereof; nor
  - (b) assign transfer sell licence or otherwise grant any rights in or to the United States Patent Application to any other person firm or company without first unconditionally offering to assign transfer sell licence or otherwise grant any such rights in or to the United States Patent Application to Boots on the same or substantially similar terms and conditions as are being offered by such other person firm or company.

4. INTELLECTUAL PROPERTY

- 4.1 Without prejudice to the provisions of Clauses 2 and 3 above which shall override all other provisions relating to the Patent Application the United States Patent Application and/or the Information and the Intellectual Property Rights therein:-
- (a) Dr On acknowledges and agrees that all or part of the Information may be protectable by Intellectual Property Rights and that all such Intellectual Property Rights in the Information shall belong to Boots; and
  - (b) Dr On hereby further unconditionally waives all of her moral rights in relation to all of the Information and/or the Patent Application in which Intellectual Property Rights exist.



- 4.2 If Boots requires access to any relevant background know-how or information owned by Dr On in order to evaluate or exploit effectively the Patent Application the United States Patent Application the Information and/or the Research Dr On will grant for this specific purpose a royalty-free non-exclusive licence to Boots for the use of any such background know-how or information that she is free to licence.
- 4.3 If Boots requires for any other purpose access to any other background know-how or information owned by Dr On but not dealt with in this Agreement Dr On expresses her willingness to grant a separate licence to Boots or such other person firm or company as Boots may nominate for such purpose upon fair and reasonable commercial terms.

5. WARRANTIES

Dr On warrants and undertakes that she has full, free and unencumbered title to and Intellectual Property Rights in the Patent Application the United States Patent Application the Research and the Information.

6. CONFIDENTIALITY

- 6.1 Dr On hereby agrees and undertakes to treat as strictly confidential and secret and not at any time (whether before or after termination hereof) disclose or permit to be disclosed to any person or otherwise make use of the Confidential Information
- 6.2 The obligations of Dr On under this clause shall survive expiry or termination of this agreement for whatever reason but shall not apply to any part of the Confidential Information which is in the public knowledge, or subsequently comes into the public knowledge, other than by breach by Dr On of the provisions of this Clause 6.

7. COMMERCIAL EXPLOITATION AND ROYALTIES

- 7.1 It is acknowledged by the parties that Boots may or may not commercially exploit the Product under the Patent Application and/or any Patent resulting therefrom. If Boots does commercially exploit the Product under the Patent Application and/or

any Patent resulting therefrom Boots will pay to Dr On a royalty equal to 1.5% of the Net Sales of the Product.

7.2 Any royalties payable to Dr On hereunder shall be payable Quarterly in arrears and shall be paid by Boots in sterling in the United Kingdom not later than 60 days after the last day of the relevant Quarter. Each payment of royalties made hereunder shall be accompanied by a statement setting out in reasonable detail the manner in which the royalty payable in respect of that Quarter has been calculated.

7.3 Any part of the Net Sales which were received by Boots in a currency other than Pounds Sterling shall be converted into Pounds Sterling at the middle rate of exchange prevailing at the close of business on the last business day of the third month of the relevant Quarter.

#### 8. TERMINATION

Either party may forthwith upon giving written notice to the other ("the defaulting party") terminate this agreement in any of the following events:-

- 8.1 the defaulting party is in breach of any of the provisions of this Agreement and such breach (if capable of remedy) shall continue seven days after notice in writing specifying the breach and requiring the same to be remedied has been given by the other party;
- 8.2 the defaulting party becomes unable to pay its debts or becomes insolvent or commits any act of bankruptcy or any petition or receiving order in bankruptcy is presented or made against it or it makes or seeks to make any composition or arrangement with its creditors or any judgement for a monetary sum given against the defaulting party is not paid out within 21 days;
- 8.3 the defaulting party ceases or threatens to cease to carry on the whole or any material part of its business; or
- 8.4 the defaulting party is prevented from carrying out its duties hereunder by reason of any incapacity for a period in excess of one month.

- 8.5 Notwithstanding termination of this Agreement the provisions of Clauses 3, 4, 5, 6 and 7 hereof shall continue in full force and effect.

9. ASSIGNMENT

- 9.1 Boots may assign any of its rights or obligations hereunder to any other person firm or company.
- 9.2 This agreement is personal to Dr On who shall not without Boots' prior written consent assign any of her rights or obligations hereunder and any purported or attempted assignment by Dr On or transfer by operation of law without such consent shall give Boots the right to terminate this agreement forthwith by notice in writing.
- 9.3 This agreement shall be binding on the permitted assignees and successors of the parties hereto

10. APPLICABLE LAW

The construction interpretation meaning validity and performance of this agreement shall be governed by the laws of England which is agreed to be the applicable law of this Agreement and the parties hereto submit to the non-exclusive jurisdiction of the English Courts.

11. NOTICES

- 11.1 Any notice request or other communication required to be given under this agreement shall be made in writing and may be hand-delivered or sent by pre-paid first class post to the recipient at the address first set out in this agreement or such other address within the United Kingdom that either party may notify to the other in writing for this purpose.
- 11.2 Notice shall be deemed to have been received:-
- (a) if sent by post 3 business days after the date of posting; and

(b) if delivered by hand on the date of delivery.

11.3 It shall be sufficient in proving service that the letter containing the notice was properly addressed and (as the case may be) put in the post, delivered or transmitted.

12. GENERAL

12.1 No relaxation, forbearance, delay or indulgence by either party in exercising its rights under this agreement or any granting of time by such party shall prejudice or affect its rights hereunder. No waiver of any default or breach under this agreement or failure to enforce any rights by either party shall constitute a waiver of any subsequent or continuing default or breach. No waiver shall be effective unless made in writing agreed and signed on behalf of the party so granting the waiver.

12.2 The headings in this agreement are solely for convenience and reference and shall not be taken into account in the construction interpretation or meaning of this agreement.

12.3 This Agreement (together with any documents referred to herein) supersedes any preliminary or previous correspondence, negotiations, arrangements or agreements between the parties in relation to the matters specifically dealt with herein and represents the entire understanding of the parties in relation to the matters specifically dealt with herein.

12.4 No amendment to or alteration of this agreement shall be effective unless made in writing agreed and signed on behalf of each of the parties hereto.

12.5 It is hereby certified that the transaction hereby effected does not form part of a larger transaction or series of transactions in respect of which the amount or value or aggregate amount or value of the consideration exceeds £60,000.

AS WITNESS the parties hereto have executed and delivered this Agreement the day and year first before written

## SCHEDULE

## ASSIGNMENT

THIS ASSIGNMENT is made the            day of                                 1998 BETWEEN Dr Ninh  
On of 36 Spray Street Woolwich London SE18 6AG ("the Assignor") (1) and The Boots  
Company PLC whose registered office is at Nottingham NG2 3AA ("the Assignee") (2).

WHEREAS

The Assignor is the proprietor of the United Kingdom Patent Application No. 9613410.1 dated 23 June 1996 entitled ("the Patent Application")

AND WHEREAS

The Assignor has agreed to assign the Patent Application to the Assignee

NOW THIS AGREEMENT WITNESSETH that in consideration of the payment of the sum of £10,000 (Ten Thousand Pounds Sterling) (the receipt of which is hereby acknowledged by the Assignor) the Assignor hereby assigns transfers and conveys unto the Assignee the Patent Application, together with the Assignor's full right title and interest therein, free of all encumbrances TO HOLD unto the Assignee absolutely.

It is hereby certified that the transaction hereby effected does not form part of a larger transaction or series of transaction in respect of which the amount or value or aggregate amount or value of the consideration exceeds £60,000.

IN WITNESS WHEREOF this assignment has been executed by the Assignor and Assignee the day and year first above written

Signed by DR NINH ON  
in the presence of:-

Signed by  
For and on behalf of  
The Boots Company PLC  
in the presence of:-

Approved for signature  
IS THOMSON

Signed by I. A. Hawtin )

For and on behalf of )

THE BOOTS COMPANY PLC )

In the presence of:- )

C.J. Wainman



Signed by DR NINH ON )

In the presence of:- )

